REMARKS

This document is submitted in response to the Office Action mailed June, 10, 2005 ("Office Action"). Applicants have amended claims 33 and 34, and have added claims 41-59. Support for the amendments to claims 33 and 34 and the new claims can be found in the original claims and in the Specification, e.g., page 9, lines 25-27; page 10, lines 1-12; page 20, Table 4; Fig. 4; page 11, lines 19-27; and page 12, lines 1-4. No new matter has been added.

Upon entry of the proposed amendments and new claims, claims 33-35 and 41-59 will be pending and under examination. Reconsideration of the application is respectfully requested in view of the remarks below.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 33-35 have been rejected as allegedly lacking enablement. Applicants respectfully traverse the grounds for the rejection in two parts below.

I

Independent claims 33 and 34 are product-by-process claims each drawn to a pharmaceutical composition containing a product prepared from a culture of the fungus *Antrodia camphorata*.

The Office Action states that "Applicant[s] [are] **required to submit the structure of the products per se** in the claimed pharmaceutical composition having 'fungal molecules having molecular weights of no more than about 10 kDa.' There is no way to do a proper search and examination for the claimed subject matter drawn to these unknown products." See page 2, lines 19-22; emphasis original. Applicants respectfully disagree.

Applicants submit that a "proper search" of the prior art for the products of claims 33 and 34 can be conducted based on specific limitations recited in the claims, i.e., the product is a pharmacologically active preparation from *Antrodia camphorata* in which all molecules have molecular weights of 10 kDa or less (claim 33) or 1 Kda or less (claim 34).

Applicants submit that the claimed products are novel over prior art compositions. In this regard, the most relevant prior art of which Applicants are aware is Wu *et al* (1997) submitted as reference "AQ" in the IDS filed October 30, 2003.

II

The Office Action further remarks that "[c]laims 33-35 are rejected under 35 U.S.C. § 112, first paragraph, because the [S]pecification, while being enabling for fraction(s) as noted by the [S]pecification examples, does not reasonably provide enablement for the claimed subject matter without specificity of the process conditions to obtain the pharmacologically active fraction compositions." See page 3, lines 2-5; emphasis added.

Applicants respectfully disagree. The Specification provides highly specific process conditions for growth of *Antrodia camphorata*, e.g., at page 7, lines 6-26; page 9, lines 12-27; and page 10, lines 1-12. Further, methods for size-based separation of molecules are well established in the art and exemplified by techniques mentioned in the Specification, such as gel filtration, density gradient purification, ultrafiltration, and ultracentrifugation. See, e.g., page 11, lines 14-18.

Based on the above remarks, Applicants submit that the Specification does indeed enable claim 33. For at least the same reasons, amended claim 34, as well as claim 35 dependent from it, is also enabled.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 33-35 were rejected as allegedly indefinite.

The Office Action states:

> The active compositions are products-by-process defined by the processes of its preparation but the claims lack sufficient information or limitations to define the composition that is isolated . . . Since any given biological source contains a multiple of possible active fractions as [indicated], each with its own particular properties, the nature of the resulting [active] fraction will depend on the conditions to obtain the fractions. Applicant[s] will be required to submit a sufficient number of properties for the claimed "active composition(s)" or "active fraction(s). See page 4, lines 2-11, emphasis added.

Applicants note that based on the limitations recited in claim 33, the claimed composition contains an *Antrodia camphorata* product that has pharmacological activity, and contains molecules having molecular weights of 10 kDa or less. Thus, they submit that a sufficient number of properties of the claimed composition has been provided to adequately define it.

Accordingly, Applicants submit that amended claim 33 is definite. For at least the same reasons, claim 34, as well as claim 35 dependent from it, is also definite.

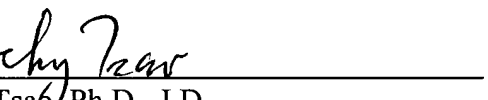
CONCLUSION

Based on the remarks set forth above, Applicants submit that amended claims 33-35 and new claims 41-60 cover allowable subject matter. Early allowance by the Examiner is respectfully solicited.

Enclosed is a $50 check for excess claim fees and a $60 check for a one month Petition for Extension of Time fee is attached. Please apply any charges to deposit account 06-1050, referencing attorney docket 11702-003006.

Respectfully submitted,

Date: 10-11-05



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